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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
3773	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,507	ANDREAS ET AL.	
	Examiner	Art Unit	
	JING OU	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-13 and 15-20* is/are pending in the application.

4a) Of the above claim(s) *4 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-13, and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the amendment along with REC filed on July 11, 2008. Claims 1-20 are pending. Claims 1 and 11 are independent. Claims 4 and 14 are withdrawn from consideration.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/11/2008 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In Claims 1 and 11, support for the recitation "wherein the outer surface of the shuttle is free of surface features that prohibit positioning of a stent segment along the outer surface, and wherein the outer surface of

the shuttle is adapted to allow a pair of adjacent stents to be positioned into direction engagement with one another" is not found in the original specification and is considered as new matter. Both paragraph 43 of the specification and Figure 4 do not provide sufficient support for the newly added recitations in Claims 1 and 11.

Claim Rejections - 35 USC § 103

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-2, 5-12, 15-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Keith et al (US Pat. No.: 6,070,589).

In regard to claim 1-2, 5-12, 15-18 and 20, Chermoni discloses:

A) a stent delivery device for delivering a plurality of stent segments to a treatment site, the device comprising: a catheter shaft (124, Fig. 1) having a proximal end and a distal end; an expandable member (balloon, 104, Fig. 7) coupled with the catheter shaft near the distal end; a shuttle (carriage, 605, Fig. 7) disposed coaxially over at least part of the catheter shaft and the expandable member, at least part of the shuttle being radially expandable (Para. [0042]), wherein the outer surface of the shuttle is free of surface features that prohibit positioning of a stent segment along the outer surface, and wherein the outer surface of the shuttle is adapted to allow a pair of adjacent stents to be positioned into direction engagement with one another (the outer surface of the shuttle 605 is free of surface features that prohibit positioning of a stent segment along the outer surface. The outer surface of the shuttle is adapted to allow a pair of adjacent stents to be positioned into direct engagement with one another because a pair of adjacent stent can be positioned into direct engagement with one another when a second stent of the pair of adjacent stent is deployed on inner side of a first stent of the pair of adjacent stent at the same location after the first stent is deployed on the blood vessel); and a plurality of stent segments (206a, 206b, 206c, Fig. 7) disposed along the shuttle;

B) the shuttle is slidably disposed over at least part of the catheter shaft and the expandable member (Para. [0041]);

C) the stent segments are fixed to the shuttle until they are expanded into a deployed position (Paras.[0041]-[0042]);

D) the stent segments are slidable (Para.[0041]), the device further comprising a stent-pushing member (106, Fig. 7), proximal to the plurality of stent segments.

E) the shuttle further comprises an abutment (barrier, next to 610a, Fig. 7) at or near a distal end of the shuttle for preventing the plurality of stent segments from being advanced beyond the distal end of the shuttle;

Chermoni does not appear to disclose:

A) an axially movable sheath disposed over at least part of the catheter shaft and the expandable member and moving the sheath axially toward the proximal end of the catheter shaft allows at least part of the expandable member to expand against the shuttle to cause the shuttle to radially expand, thus causing at least one of the plurality of stent segments to expand; the sheath having a reinforced distal portion; and

B) a sheath disposed over the shuttle.

The recitations, "adapted to resist radial expansion of the expandable member " and " while a remaining portion of the expandable member is constrained by the sheath" in Claim 1; "the sheath is adapted to expose a first portion of the expandable member to deploy a first selected number of stent segments" in Claim 6; and "the sheath is adapted to further expose at least a second portion of the expandable member to deploy a second selected number of stent segments" in Claim 7; are intended use recitations. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim limitation.

However, Keith et al explicitly teach:

A) an axially movable sheath (delivery sheath, 60R, Fig. 11) disposed over at least part of the catheter shaft (lead balloon catheter, 68R, Fig. 4) and the expandable member (balloon, 70R, Fig. 4) and moving the sheath axially toward the proximal end of the catheter shaft allowing at least part of the expandable member to expand, thus causing a stent (aortic stent, 64R, Fig. 4) to expand (Col. 12, lines 48-51, the expansion of the balloon causes the stent to expand); and the sheath having a reinforced distal portion (Col. 6, lines 65-67 and Col. 7, lines 1-2, Keith et al discloses a sheath having a reinforced layer throughout the sheath); and

B) the sheath is disposed over the distal portion of the outer shaft of catheter that carries the stent (Figs. 4 and 11).

In addition, the sheath of Keith et al meets the functional limitation, "a remaining portion of the expandable member is constrained by the sheath." (Col. 7, lines 6-11 and Figs. 10-13)

Chermoni and Keith et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chermoni and Keith et al before him or her, to modify the stent delivery device of Chermoni to include an axially movable sheath and replace

the stent push member of Chermoni by a pusher tube (ledge, 72, Fig. 4) as taught by Keith et al.

The suggestion/motivation for modifying a sheath to include a reinforced layer would have been to add column strength or kink resistance (Col. 6, lines 65-67 and Col. 7, lines 1-2). Applicant should note that it is well-known in the art that an axial movable sheath is used to keep a stent to remain unexpanded and prevent a stent from deploying at an undesired location. It is also well-known that a pusher tube/ledge is used to push the stent out a sheath.

Therefore, it would have been obvious to combine Keith et al with Chermoni to obtain the invention as specified in the instant claims.

8. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Keith et al (US Pat. No.: 6,070,589) as applied to claims 1 and 11 above, and further in view of Shaknovich (US Pat. No.: 5,807,398).

In regard to claims 3 and 13, Chermoni and Keith et al disclose all the limitations of the claim as taught above but fail to disclose that the shuttle is fixedly disposed over at least part of the catheter shaft and the expandable member.

However, Shaknovich explicitly discloses a shuttle (1, Fig. 1) that is fixedly disposed over at least part of the catheter shaft (7, Fig. 1) and the expandable member (8, Figs 1 and 4 and Col. 4, lines 22-31).

Chermoni, Keith et al, and Shaknovich are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Chermoni, Keith et al, and Shaknovich before him or her to modify the stent delivery device of Chermoni and Keith et al to include a shuttle that is fixedly disposed over at least part of the catheter shaft and the expandable member of Shaknovich.

The motivation/suggestion for doing so would have been to be advanced into a patient as a shuttle-balloon catheter assembly (Shaknovich, Col. 11, lines 1-16).

Therefore, it would have been obvious to combine Shaknovich with Chermoni and Keith et al to obtain the invention as specified in the instant claims.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Keith et al (US Pat. No.: 6,070,589) as taught in Claim 11, and further in view of Martinez et al (US Pat. No.: 5,593,412).

In regard to Claim 19, Chermoni in view of Keith et al discloses all the limitations the claim as taught above but fails to disclose at least one valve member coupled with the sheath for selectively retaining at least one stent segment within the sheath.

However, Martinez et al explicitly discloses valve members coupled with the sheath (51-55, Fig. 2B).

Chermoni, Keith et al, and Martinez et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chermoni in view of Keith et al and Martinez et al before

him or her, to modify the stent delivery device of Chermoni in view of Keith et al to include the valve members coupled with the sheath as taught by Martinez et al., because it is well-known in the art that the valve members coupled with the sheath keep the stent from premature deployment.

Therefore, it would have been obvious to combine Martinez et al with Chermoni and Keith et al to obtain the invention as specified in the instant claim.

10. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Keith et al (US Pat. No.: 6,070,589) as taught in Claim 11, and further in view of Palermo (US Pat. No.: 5,312,415)

In regard to Claim 19, Chermoni in view of Keith et al discloses all the limitations the claim as taught above but fails to disclose at least one valve member coupled with the sheath for selectively retaining at least one stent segment within the sheath.

However, Palermo explicitly discloses a sheath with a constricted distal end (104, Fig. 1).

Chermoni, Keith et al, and Palermo are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chermoni in view of Keith et al and Palermo before him or her, to modify the stent delivery device of Chermoni in view of Keith et al to include a sheath with a constricted distal end as taught by Palermo.

The suggestion/motivation for doing so would have been to control the discharge of the coil through the catheter sheath distal tip (Palermo, Col. 3, lines 67-68 and Col. 4, lines 1-3)

Therefore, it would have been obvious to combine Palermo with Chermoni and Keith et al to obtain the invention as specified in the instant claim.

11. Claims 1-3, 5-9, 11-13, 15-17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich (US Pat. No.: 5,807,398) in view of Keith et al (US Pat. No.: 6,070,589).

In regard to Claims 1-3, 5-9, 11-13, 16-17, and 20, Shaknovich discloses a stent catheter system, comprising: a catheter shaft (7, Fig. 4), an expandable member (balloon, 8, Fig. 4), an axially movable sheath (13, Fig. 6), a shuttle (1, Fig. 1), a plurality of stent segments (3a, Fig. 9); wherein the outer surface of the shuttle is free of surface features that prohibit positioning of a stent segment along the outer surface, and wherein the outer surface of the shuttle is adapted to allow a pair of adjacent stents to be positioned into direction engagement with one another (the outer surface of the shuttle 1 is free of surface features that prohibit positioning of a stent segment along the outer surface. The outer surface of the shuttle is adapted to allow a pair of adjacent stents to be positioned into direct engagement with one another because a pair of adjacent stent can be positioned into direct engagement with one another when a second stent of the pair of adjacent stent is deployed on inner side of a first stent of the pair of adjacent stent at the same location after the first stent is deployed on the blood vessel), wherein the shuttle is slidably disposed over at least part of the catheter shaft

and the expandable member when the expandable member is deflated, the shuttle is fixedly disposed over at least part of the catheter shaft and the expandable member when the expandable member is inflated, the stent segments are fixed to the shuttle until they are expanded into a deployed position, and the stent segments are slidably disposed along the shuttle when the expandable member is deflated.

Shaknovich fails to explicitly disclose that the sheath has a reinforced distal portion and a stent-pushing member.

However, Keith et al teaches a stent delivery system, comprising: a sheath (delivery sheath, 60R, Fig. 11) having a reinforced distal portion (Col. 6, lines 65-67 and Col. 7, lines 1-2, Keith et al discloses a sheath having a reinforced layer throughout the sheath) and a stent-pushing member (ledge, 72R, Fig. 4).

Shaknovich and Keith et al are analogous art because they are from the same field of endeavor.

Therefore, it would have been obvious to combine Keith et al with Shaknovich to obtain the invention as specified in the instant claims. The suggestion/motivation for modifying the sheath of Shaknovich to include a reinforced layer as taught by Keith et al would have been to add column strength or kink resistance (Keith et al, Col. 6, lines 65-67 and Col. 7, lines 1-2). Applicant should have noted that it is old and well-known that a pusher tube/ledge located on the proximal end of a stent is used to push the stent out a sheath.

12. Claims 10 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich (US Pat. No.: 5,807,398) in view of Keith et al (US Pat. No.: 6,070,589) as

applied to claims 1 and 11 above, and further in view of Chermoni (US Pub. No.: 2002/0156496).

In regard to Claims 10 and 18, Shaknovich in view of Keith et al discloses all the limitations of the claims but fails to teach an abutment at or near a distal end of the shuttle.

However, Chermoni explicitly teaches an abutment (the protrusion/barrier at the most distal end of the carriage/shuttle 605 as shown in Fig. 6) at or near a distal end of the shuttle.

Therefore, it would have been obvious to combine Chermoni with Shaknovich and Keith et al to obtain the invention as specified in the instant claims. Applicant should have noted that it is old and well-known that such abutment would have been to provide a barrier to prevent the stent segments from being advanced beyond the distal end of the shuttle.

13. Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich (US Pat. No.: 5,807,398) in view of Keith et al (US Pat. No.: 6,070,589) as applied to claim 11 above, and further in view of Palermo (US Pat. No.: 5,312,415)

In regard to Claim 19, Shaknovich in view of Keith et al discloses all the limitations the claim as taught above but fails to disclose at least one valve member coupled with the sheath for selectively retaining at least one stent segment within the sheath.

However, Palermo explicitly discloses a sheath with a constricted distal end (104, Fig. 1).

Shaknovich, Keith et al, and Palermo are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Shaknovich in view of Keith et al and Palermo before him or her, to modify the stent delivery device of Shaknovich in view of Keith et al to include a sheath with a constricted distal end as taught by Palermo.

The suggestion/motivation for doing so would have been to control the discharge of the coil/ stent /vascular device through the catheter sheath distal tip (Palermo, Col. 3, lines 67-68 and Col. 4, lines 1-3)

Therefore, it would have been obvious to combine Palermo with Shaknovich and Keith et al to obtain the invention as specified in the instant claim.

Response to Arguments

14. Applicant's arguments filed 07/11/2008 have been fully considered but they are not persuasive. The allegation on page 7 of the remarks that Chermoni fails to teach or suggest a shuttle "wherein the outer surface of the shuttle is free of surface features that prohibit positioning of a stent segment along the outer surface, and wherein the outer surface of the shuttle is adapted to allow a pair of adjacent stents to be positioned into direction engagement with one another" is incorrect. Chermoni discloses the outer surface of the shuttle 605 is free of surface features that prohibit positioning of a stent segment along the outer surface. The outer surface of the shuttle in Chermoni is adapted to allow a pair of adjacent stents to be positioned into direct engagement with one another because a pair of adjacent stent can be positioned into direct engagement

with one another when a second stent of the pair of adjacent stent is deployed on an inner side of a first stent of the pair of adjacent stent at the same location after the first stent is deployed on the blood vessel. Therefore, the annular depressions in Chermoni would not prohibit a pair of adjacent stents to be positioned into direction engagement with one another. The allegation on pages 8 and 11 of the remarks that Shaknovich fails to teach or suggest that the shuttle is fixedly disposed over at least part of the catheter shaft and the expandable member is incorrect. Shaknovich teaches or suggests that the shuttle is fixedly disposed over at least part of the catheter shaft and the expandable member (Col. 11, lines 10-16, "the shuttle is retained on the shaft of the balloon catheter"). Besides, the shuttle in Shaknovich is fixedly disposed over at least part of the catheter shaft and the expandable member when the expandable member is inflated.

The allegation on page 11 of the remarks that Shaknovich fails to teach or suggestion a shuttle "wherein the outer surface of the shuttle is free of surface features that prohibit positioning of a stent segment along the outer surface, and wherein the outer surface of the shuttle is adapted to allow a pair of adjacent stents to be positioned into direction engagement with one another" is incorrect. Shaknovich discloses the outer surface of the shuttle 1 is free of surface features that prohibit positioning of a stent segment along the outer surface. The outer surface of the shuttle in Shaknovich is adapted to allow a pair of adjacent stents to be positioned into direct engagement with one another because a pair of adjacent stent can be positioned into direct engagement with one another when a second stent of the pair of adjacent stent is deployed on an

inner side of a first stent of the pair of adjacent stent at the same location after the first stent is deployed on the blood vessel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO

/Julian W. Woo/
Primary Examiner, Art Unit 3773

September 2, 2008